Remarks

Following entry of this amendment, claims 12, 17 and 18 are pending. Claim 12 has been amended. Support for the amendment of claim 12 can be found throughout the specification, for example at page 2, line 20, and page 3, lines 10-13.

New claims 17 and 18 are added herein. Support for new claims 17-18 can be found throughout the specification, for example at page 6, lines 6-15. New claims 17-18 parallel claim 16, which is withdrawn from consideration.

No new matter is introduced by the foregoing amendments. After entry of this amendment, claims 12 and 17-18 are pending in this application. Consideration of the pending claims is requested.

Priority Claim

Applicants thank the Examiner for acknowledging that the priority claim has been perfected.

Information Disclosure Statement

Applicants thank the Examiner for noting that Elliot et al. was published in volume 88. As this reference has been initialed on the form PTO-1449, it is the Applicants understanding that this reference has been considered by the Examiner.

Specification

Page 9 of the specification is objected to for including a typographical error. Page 9 of the specification is amended herein to correct the typographical error in the word "concern." Applicants submit that this amendment removes the objection.

Claim Objections

Claim 12 is objected to for not including a comma between the phrases "a covalent coupling" and "and a non covalent association." Claim 12 is amended herein to include the comma as requested in the Office action, thereby removing the objection.

Rejections Under 35 U.S.C. § 112

Claim 12 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly "a microtubule binding function" is indefinite. Applicants respectfully disagree with this rejection, as they believe that the recitation of "a" is required for proper claim format. However, solely to advance prosecution, the phrase "a microtubule binding function" has been replaced with the phrase "binds microtubules." Applicants submit that the amendment renders the rejection moot.

Claim 12 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly the specification provides insufficient written support for all herpesviral proteins that binds VP22. The Office action alleges that only HSV1 VP22 protein is described by the specification. Applicants respectfully disagree with this assertion. Applicants submit that the specification clearly discloses other herpesviral proteins. For example, the VP22 proteins of HSV type 2, bovine herpesvirus (BHV) and Marek's disease virus (MDV) are disclosed in the specification on page 16, lines 10-14. One of skill in the art could readily could readily test a fragment of the VP22 proteins from these viruses to ascertain microtubule binding function without the need for undue experimentation. However, solely to advance prosecution, claim 12 has been amended to recited that the VP22 protein is a HSV1 VP22 protein.

Claim 12 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly the specification does not provide sufficient written description for fragments and derivatives of HSV. The Office action points to section 2163 of the Manual of Patent Examination Procedure (MPEP) in support of the argument that insufficient written description is provided for fragments of HSV. Applicants respectfully disagree with this assertion.

MPEP § 2163 states that written description requirement for a genus is met when the specification provides (1) sufficient description of "a representative number of species by actual reduction to practice," and by (2) disclosure of "relevant identifying characteristics" such as "functional characteristics coupled with a known or disclosed correlation between structure and function." Applicants submit that with regard to fragments and of HSV1 VP22, the present specification provides both (1) the disclosure of a representative number of species and (2) a

correlation of a functional characteristic (microtubule binding) with structure (amino acids 160-173).

With regard to the description of a representative number of species, the specification discloses that fragments of amino acids 1-267 of HSV1 VP22 retains the microtubule binding function of VP22 (see page 15, line 13-15). In addition, a fragment of amino acids 1-191 (plus amino acid 192 mutated to leucine) of HSV VP22 bound microtubules, albeit not as efficiently as wild-type VP22 (see the specification at page 15, lines 16-17). The specification also discloses that a fragment of amino acid 1-172 retained to some degree that ability of VP22 to bind to microtubules (see page 15, lines 25-28). Thus, a representative number of fragments/variants of VP22 that bind microtubules have been described.

With regard to the correlation of a functional characteristic (in the present application, microtubule binding) with structure, the specification discloses that mutant full-length HSV1 VP22 that does not include amino acids 160-173 (but included three spacer residues) has substantially reduced ability to bind microtubules (see page 15, lines 29-33). The specification further describes that fragments of amino acids 1-119 of HSV1 VP22 or amino acids 1-159 of HSV1 VP22 did not retain the ability to bind microtubules (see page 15, lines 29-30). The specification discloses that amino acids 160-173 of HSV1 VP22 are important for microtubule binding, and that deletion of these residues eliminates (or substantially reduces) microtubule binding. Thus, a clear correlation between the structure (amino acids 160-173) and function (microtubule binding) has been demonstrated.

Thus, the Applicants submit that the requirements of MPEP § 2163 have been met. A representative number of portions of the HSV1 VP22 protein that bind microtubules have been produced and tested, and are disclosed in the specification. In addition, a correlation between structure (amino acid sequence) and function has been demonstrated. Thus, the Applicants submit that the specification provides sufficient written description for fragments and variants of HSV1 VP22 that bind microtubules. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Claim 12 is rejected as allegedly being anticipated by PCT Publication No. WO 97/05265 (hereinafter "the 265 publication) or Elliot et al. (Cell 83:223-233). According the Office action,

the cited references teach a method wherein VP22 variants are transported among cells to deliver an antibody epitope. The Office action alleges that as VP22 inherently binds microtubules the process described in the references inherently anticipates claim 12.

Applicants respectfully disagree with this rejection as applied to claim 12 as amended. Claim 12 is amended herein to be limited to the transport of microtubule binding drugs using HSV1 VP22. There is nothing in the '265 publication or Elliot et al. that discloses, or renders obvious, the introduction of microtubule binding drugs into cells using VP22. Thus, reconsideration and withdrawal of the rejections are respectfully requested.

Obviousness-type Double Patenting Rejections

Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 6-8 of U.S. Patent No. 6,184,038. Claim 12 is also rejected under the judicially created doctrine of obviousness-type double patenting over claim 16 of U.S. Patent No. 6,017,735. Claim 12 is further rejected over the judicially created doctrine of obviousness-type double patenting over claim 10 of U.S. Patent No. 6,251,398. Applicants respectfully disagree with these rejections as applied to claim 12 as amended.

Claim 12 is amended herein to be directed to a method for delivering a microtubule binding drug and to be limited to HSV1 VP22 proteins and fragments thereof. Applicants submit that the amendment of claim 12 renders the obviousness-type double patenting rejections moot. Reconsideration and withdrawal of the rejections is respectfully requested.

Conclusion

It is respectfully submitted that the present claims are in a condition for allowance. If any issues remain, the Examiner is requested to contact the undersigned attorney prior to issuance of the next Office action in order to arrange a telephone interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution and allowance of the claims.

Respectfully submitted,

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